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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,767	09/05/2006	Sabrina Higgins	102792-532/11160P1US	6304
27389 PARFOMAK, A	7590 05/14/201 <b>ANDREW N</b> .	EXAMINER		
NORRIS MCLAUGHLIN & MARCUS PA			ROONEY, NORA MAUREEN	
875 THIRD AVE, 8TH FLOOR NEW YORK, NY 10022			ART UNIT	PAPER NUMBER
,			1644	
			MAIL DATE	DELIVERY MODE
			05/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/595,767	HIGGINS ET AL.				
Office Action Summary	Examiner	Art Unit				
	NORA M. ROONEY	1644				
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period was period for reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>02 Fe</u>	ebruary 2010					
	action is non-final.					
·=						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	•					
4)⊠ Claim(s) <u>1-13</u> is/are pending in the application.						
4a) Of the above claim(s) <u>9.10 and 13</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>——</u> is/are allowed. 6)⊠ Claim(s) <u>1-8 and 11-12</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers	•					
··· _						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
,—	anniner. Note the attached Office	Action of form F 10-132.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)	<b>"</b> □	(DTO 440)				
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) ☐ Interview Summary Paper No(s)/Mail Da					
3) Information Disclosure Statement(s) (PTO/SB/08)	5) 🔲 Notice of Informal P					
Paper No(s)/Mail Date 6) Other:						

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## **DETAILED ACTION**

1. Applicant's response filed on 02/02/2010 is acknowledged.

- 2. Claim 13 stands withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and claims 9-10 stand withdrawn as being directed to a non-elected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/10/2009.
- 3. Claims 1-8 and 11-12 are currently under consideration as they read on a method of deactivating an allergen comprising dispersing into an airspace capable or able to support said allergen an allergen-deactivating amount of a deactivant comprising citrus oil or lemon grass oil.

## **Double Patenting**

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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5. Claims 1-8 and 11-12 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 10-11 and 19 of copending Application No.10/597,448. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-8 and 11-12 are directed to a method of deactivating an allergen, the method comprising: dispersing into an airspace capable or able to support said allergen an allergen-deactivating amount of a deactivant an allergen deactivating compound comprising one or more of the following materials: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot; and oil of lemon grass. and claims 7, 10-11 and 19 are directed to a method for treating an allergen-contaminated inanimate substrate comprising: dispersing an allergen-reducing amount of an allergendeactivating compound dispersed into an airspace in at which an allergen-contaminated inanimate substrate is located, to provide achieve a prolonged reduction in the allergen loading of the substrate, wherein the reduction after 14 days is at least as great as the initial reduction of claim wherein the deactivant is selected from: a citrus oil including orange oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot; and oil of lemon grass or a component thereof.

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Applicant's response filed on 02/02/2010 has been fully considered, but is not found persuasive.

Applicant argues:

"Applicants respectfully traverse the Examiner's "double patenting" rejection of the foregoing claims in view of copending U.S. Application No. 10/597448 (hereinafter "the copendiag 448 application") which is commonly assigned with the present application. Applicants point out that to date, no claims ha the instant application or the 448 application have been cited as being allowable. As such it is thus believed that the Examiner's issuance of a "double patenting" rejection is improper as being premature. Applicants believe that entry of a Terminal Disclaimer at this point in time is premature, as the scope of allowable claims in the present application have not yet been established agreeing to the limitation of the term and scope of protection may be prejudicial to the rights of the applicant, e.g., wherein narrowed claims of the present application may be indicated as allowable and such claims might no longer give basis to a "double patenting" rejection. However, upon the indication of allowable subject matter, the Examiner is invited to reinstate the instant rejection, if appropriate, at such later time."

It is the Examiner's position that the rejection stands until the conflicting claims are amended, cancelled or a Terminal Disclaimer is filed.

## Claim Objections

6. Claim 8 is objected to because of the following informalities: Claim 8 recites 'a method according to claim" but does not recite a claim number. Appropriate correction is required.

## Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claims 1-8 and 11-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a method of burning orange oil using an oil burner and a method of burning candles with orange oil, spearmint oil, bois de rose oil, frankincense, oil of bergamot, oil of lemon grass, bois de rose oil and oil of bergamot, bois de rose oil and oil of lemon grass, oil of bergamot and orange oil, and oil of jasmine and orange oil in the presence of house dust; the specification does not provide reasonable enablement for : a method of deactivating an allergen, the method comprising: dispersing into an airspace capable or able to support said allergen an allergen-deactivating amount of a deactivant comprising one or more of the following materials: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot; and, oil of lemon grass of claim 1; wherein the deactivant is dispersed into the airspace as a vapour over an extended period, by the use of heat of claim 2; wherein the deactivant is dispersed via a wick dipped into a reservoir of the deactivant of claim 3; wherein the deactivant is provided as a water-in-oil emulsion containing up to 2% by weight of one or more of: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot; and, oil of lemon grass of claim 4; wherein the deactivant is incorporated into a candle of claim 5; wherein the candle comprises at least 2% by weight of one or more of: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot; and, oil of lemon grass of claim 6; wherein the deactivant is dispersed into the airspace on two or more separate periods of claim 7; a method according to claim, wherein the deactivant is one or more asextracted oils selected from: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot; and, oil of lemon grass of claim 8; a method deactivating an allergen at a locus of one or more of the following materials: a citrus oil; a mint oil; bois de rose oil; oil of

jasmine; frankincense; oil of bergamot; and, oil of lemon *grass*, comprising the step of contacting said allergen with at least one of said materials of claim 11; and a method of deactivating allergens on a surface located within an airspace which comprises the step of: dispersing into said airspace one or more of the following materials: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot and oil of lemon grass of claim12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification on pages 10-15 discloses a series of experiments wherein essential oils in oil burners and candles were burned in the presence of house dust. Then, 16-24 hours later the house dust was used in an ELISA assay to determine the amount of Der p1 in the samples. House dust exposed to burning unfragranced candles were used as a control.

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The specification does not adequately disclose a method of deactivation any "allergen." The specification discloses a method that only measures Der p 1 in house dust. The specification does not show that any other allergen of house dust is reduced nor does it show that any other type of allergen can be been reduced by performing the claimed method. The term "allergen" encompasses a diverse genus of molecules from sources as diverse as pets, pollen, latex, drugs, metals and foods. The specification has not adequately disclosed a method whereby the genus of all allergens encompassed will be "deactivated" as a result of the instant method. The art of Blumenthal et al. (PTO-892, Reference U) teaches the definition of an allergen (In particular, whole document). As such, the art is unpredictable and one of ordinary skill in the art would be required to perform undue experimentation to practice the invention of deactivating any allergen commensurate in scope with the claims.

The specification is not enabled for a method of "deactivating" an allergen. There is no limiting definition in the specification for the term "deactivating" such that one of ordinary skill in the art could perform the method without undue experimentation. The specification seems to disclose that there is actually less Der p 1 in the dust samples exposed to the claimed method. However, reducing the amount of allergen is not the same as 'deactivating' an allergen. The term 'deactivating' implies that the allergens have lost their function, not that there is less of the allergen. Blumenthal et al. (PTO-892; Reference U) teaches how allergens function in vivo and in vitro and also teaches that correlations between structure and IgE binding (or the lack of IgE binding) cannot be predicted on an a priori structural basis (PTO-892, Reference U, see entire

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document and page 39 of third full paragraph). There is no indication in the specification that shows that any allergen has lost any of its functions or has become less allergenic through exposure to the claimed method. Therefore, the specification has not adequately disclosed a method of deactivating any allergen, much less all allergens as encompassed by the instant claim recitation.

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If the specification's disclosure that there is less Der p 1 in the samples exposed to the burning candles or oil is an accurate reflection on the Der p 1 present and not an artifact of the presence of oil molecules masking allergens or any other effect, it would seem that the candles or oil might be exerting its effect on dust mites and not directly on the allergens. If the process of exposing dust to vaporizing oil kills dust mites in the dust, then decreased Der p 1 production would make sense. However, there is no indication in the specification or in the art to provide support for the claimed method of reducing allergens resulting from degradation or any other means. Furthermore, there is no indication set forth in the specification to show that the allergens themselves had been altered in any way. The specification only discloses that the amount of Der p1 is less in the treated dust. If the effect is on the dust mites themselves, then the method is not enabled for reducing the amount of allergens that are not being actively produced by mites in dust. For example, if the effect was on the production of the allergens by mites and not on the allergens themselves, then pollen allergens would not be reduced by the instant method. Given the unpredictability, one of ordinary skill in the art would be required to perform undue experimentation to practice the method commensurate in scope with the claims.

Without a testable function to determine whether or not a particular allergen has been "deactivated" one of ordinary skill in the art would be required to perform undue experimentation to determine what deactivants are encompassed by the instant claim recitations. The specification discloses the use of particular deactivants. However, the recitation of "one or more" in the claims opens up the claims to encompass a genus comprising many combination of deactivants. In order for one to determine whether or not a particular deactivant can be used, there must be a testable function. Without a recitation of a testable function, one of ordinary skill in the art would be required to perform undue experimentation to practice the invention commensurate in scope with the claims.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. Claims 1-8 and 11-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

<u>Applicant is in possession of</u>: a method of burning orange oil using an oil burner and a method of burning candles with orange oil, spearmint oil, bois de rose oil, frankincense, oil of

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bergamot, oil of lemon grass, bois de rose oil and oil of bergamot, bois de rose oil and oil of lemon grass, oil of bergamot and orange oil, and oil of jasmine and orange oil in the presence of house dust.

Applicant is not in possession of: a method of deactivating an allergen, the method comprising: dispersing into an airspace capable or able to support said allergen an allergendeactivating amount of a deactivant comprising one or more of the following materials: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot; and, oil of lemon grass of claim 1; wherein the deactivant is dispersed into the airspace as a vapour over an extended period, by the use of heat of claim 2; wherein the deactivant is dispersed via a wick dipped into a reservoir of the deactivant of claim 3; wherein the deactivant is provided as a water-in-oil emulsion containing up to 2% by weight of one or more of: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot; and, oil of lemon grass of claim 4; wherein the deactivant is incorporated into a candle of claim 5; wherein the candle comprises at least 2% by weight of one or more of: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot; and, oil of lemon grass of claim 6; wherein the deactivant is dispersed into the airspace on two or more separate periods of claim 7; a method according to claim, wherein the deactivant is one or more as-extracted oils selected from: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot; and, oil of lemon grass of claim 8; a method deactivating an allergen at a locus of one or more of the following materials: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot; and, oil of lemon grass, comprising the step of contacting said allergen with at least one of said materials

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of claim 11; and a method of deactivating **allergens** on a surface located within an airspace which comprises the step of: dispersing into said airspace one or more of the following materials: a citrus oil; a mint oil; bois de rose oil; oil of jasmine; frankincense; oil of bergamot and oil of lemon grass of claim12.

The specification has not adequately described the genus of allergens and deactivants encompassed by the instant claim recitations that can be used in the claimed allergen deactivating method.

Applicant has disclosed only a method of burning orange oil using an oil burner and a method of burning candles with orange oil, spearmint oil, bois de rose oil, frankincense, oil of bergamot, oil of lemon grass, bois de rose oil and oil of bergamot, bois de rose oil and oil of lemon grass, oil of bergamot and orange oil, and oil of jasmine and orange oil in the presence of house dust; therefore, the skilled artisan cannot envision all the contemplated allergen, deactivant and method possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or

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by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3<sup>rd</sup> column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications
Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No.
4, pages 1099-1111, Friday January 5, 2001.

- 10. No claim is allowed.
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by

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telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-

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0735. The fax number for the organization where this application or proceeding is assigned is

571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application

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system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 10, 2010

Nora M. Rooney

Patent Examiner

Technology Center 1600

/Nora M Rooney/

Examiner, Art Unit 1644